

Waiver and Modification Requests Denied by CMS

CMS has reviewed the waiver and modification requests submitted by exclusive card sponsor applicants in response to Section 3.8 of the Exclusive Card Sponsor Solicitation. CMS is denying the requests identified below, based on legal or policy determinations.

CMS is authorized to grant a waiver or modification only when the waiver is needed to avoid duplication or conflict with Part C requirements or where the waiver would improve the coordination of benefits between the drug card and the Medicare managed care plan drug benefits. Also, CMS is restricted by regulation to granting waivers only of provisions stated in 42 CFR §403.804 and §403.806.

1. **Transitional Assistance Coinsurance** - CMS does not grant the waiver requested to allow exclusive card enrollees not to pay the 5%/10% coinsurance when using their transitional assistance to pay for drugs not covered by their Medicare managed care drug plan. *Basis for Determination – There is no legal basis for this waiver as it does not affect coordination of benefits. Rather, it simply allows exclusive card enrollees to pay less out of pocket when using their TA than general card enrollees.*
2. **Retail Pharmacy/Generic Alternative Information** – CMS does not grant the requested waiver of the requirement that exclusive drug card network pharmacies provide information about the differential between a drug's negotiated price and the price of the lowest-priced generic alternative. *Basis for Determination – Applicant's justification of the waiver on the basis that providing such information is burdensome is not one of the three stated bases on which CMS may grant a waiver.*
3. **Record Retention** – CMS does not grant the requested waiver of the 6-year record retention requirement stated in 42 CFR §403.813(b). *Basis for Determination – Provisions of 42 CFR §403.813 may not be waived. Also, the Medicare Advantage record requirements at 42 CFR §422.502(e)(4) do not include the drug card provisions that obligate the sponsor to retain the records consistent with the provisions of the Privacy Rule.*
4. **Discontinuation of Current Discount Card** – CMS does not grant the requested waiver of the Medicare Advantage requirement that Medicare Advantage plans must continue to offer a discount card that CMS approved as part of the plan's ACR package. This waiver would have allowed the Card Sponsor to substitute the new Medicare-approved drug card for the card described in the ACR package. *Basis for Determination: Section 1860D-31 of the Act does not authorize waivers of Medicare Advantage program requirements.*
5. **Definition of Covered Drugs** – CMS does not grant the Card Sponsor a waiver of the definition of covered drugs at 42 CFR §403.802 for which a discount may be offered under the Medicare approval to include drugs that are covered under the Card Sponsor's existing Medicare managed care plan drug benefit. *Basis for*

Determination: Card Sponsor justified this waiver request by stating that it would allow them to improve their coordination of benefits by allowing beneficiaries to obtain discounts on certain drugs after beneficiaries have reached their drug benefit coverage limit. The drugs include: single-entity vitamins that require a prescription order or refill to be dispensed, drugs prescribed for the symptomatic relief of coughs and colds, barbiturates, and benzodiazepines. Although this waiver could be justified legally as facilitating the coordination of benefits, granting such a waiver conflicts with our policy concerning limiting the application of transitional assistance for all eligible beneficiaries to the cost of covered drugs. CMS is concerned that once granted this waiver, Card Sponsors might begin using the new definition to justify applying transitional assistance to the cost of the drugs identified above.